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International application number: PCT/US04/041407

International filing date: 28 December 2004 (28.12.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/533,004
Filing date: 29 December 2003 (29.12.2003)

Date of receipt at the International Bureau: 28 January 2005 (28.01.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

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**APPLICATION NUMBER:** ***60/533,004***
**FILING DATE:** ***December 29, 2003***
**RELATED PCT APPLICATION NUMBER:** ***PCT/US04/41407***

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13142 U.S. PTO
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**PROVISIONAL APPLICATION COVER SHEET**

**Mail St p Provisional Patent Application**
**EXPRESS MAIL NO.: EV 326694838 US**

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(c).

| Docket Number **09292.6003** | | Type a plus sign (+) inside this box → | + |
|---|---|---|---|

| INVENTOR(s)/APPLICANT(s) | | | |
|---|---|---|---|
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22387 U.S. PTO
60/533004
122903

TITLE OF INVENTION (500 characters max)

**METHODS AND SYSTEMS FOR DETECTING AN OCCLUSION**

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ENCLOSED APPLICATION PARTS (check all that apply)

| | | |
|---|---|---|
| ☒ Specification | 13 Pages | ☐ Small Entity Statement |
| ☒ Drawings | 2 Sheets<br>1-2 Figures | ☐ Other (specify) |

METHOD OF PAYMENT (check one)

| | | PROVISIONAL FILING FEE |
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| ☐ | A check or money order is enclosed to cover the Provisional filing fees | |
| ☒ | The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number 06-0916. | ☒ $160.00<br>☐ $80.00 (small entity) |

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are:

[Text]

Respectfully submitted,

SIGNATURE ____________ Date December 29, 2003

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☐ Additional inventors are being named on separately numbered sheets attached hereto.

PROVISIONAL APPLICATION FILING ONLY

Applicants: Steve P. GETZ et al.
Title: METHODS AND SYSTEMS FOR DETECTING AN OCCLUSION
Filed: December 29, 2003
Attorney Docket No.: 09292.6003
Customer No. 22,852

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By: Sherleen Goodlette
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Attachments:

1. Provisional Application Cover Sheet (1 pg)
2. Provisional Application - 13 pages, including 2 independent claims and 2 claims total
3. Drawings - 2 sheets of drawings (Figures 1-2)
4. Post Card to Acknowledge Receipt
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Attorney Docket No. 09292.6003
**EXPRESS MAIL NO.: EV 326694838 US**

# UNITED STATES PATENT APPLICATION

FOR

# METHODS AND SYSTEMS FOR DETECTING AN OCCLUSION

BY

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TITLE OF INVENTION

# METHODS AND SYSTEMS FOR DETECTING AN OCCLUSION

## BACKGROUND OF THE INVENTION

### I. Field of the Invention

[001] The present invention generally relates to detecting an occlusion. More particularly, the present invention relates to detecting an occlusion in a tube, and even more particularly to detecting an occlusion in a tube in an ambulatory infusion pump.

### II. Background Information

[002] Devices, such as ambulatory infusion pumps, may deliver material, such as insulin, through a tube and hollow needle (the infusion set) into a user's body. At times the infusion set may become blocked or "occluded". This situation may result in the user not receiving one or more full doses of insulin. Because it is medically dangerous for a patient not to receive a full dose of medication, this situation needs to be detected and the user, needs to be warned when this situation occurs.

[003] With an insulin infusion pump, for example, the force required to deliver the insulin through the infusion set increases when an occlusion is present in the system. Conventional occlusion detection methods look for the force to rise above a predetermined level, or to rise above a predetermined delta added to an initial delivery force. These methods suffer from either not detecting the occlusion early enough, or because they are too sensitive, or provides false alarms due to long slow force variations unrelated to an occlusion.

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## SUMMARY OF THE INVENTION

[004] Consistent with embodiments of the present invention, systems and methods are disclosed for detecting an occlusion in a tube.

[005] In accordance with a first preferred embodiment, a method for detecting an occlusion in a tube comprises measuring a first force needed to deliver a first material through the tube, determining that an occlusion exists in the tube if the first force is greater than a baseline value plus a delta value, the baseline value being assigned a value equal to the force necessary to deliver the first material through the tube in an un-occluded state, and the delta value being assigned a value selected to create a desired level of sensitivity if the first force is less than or equal to the baseline value plus the delta value, and in the event a turbulence factor is less than a threshold value, the baseline value is equal to a second force, the second force being a low-pass filtered version of the first force, the turbulence factor being a low-pass filtered version of the absolute value of the difference between the first force and the second force, measuring a third force needed to deliver a second material through the tube, and determining that an occlusion exists in the tube if the third force is greater than the baseline value plus the delta value.

[006] According to another preferred embodiment, a system for detecting an occlusion in a tube comprises a memory storage for maintaining a plurality of data registers, and a processing unit coupled to the memory storage, wherein the processing unit is operative to receive a first force needed to deliver a first material through the tube, and determine that an occlusion exists in the tube if the first force

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is greater than a baseline value plus a delta value, the baseline value being assigned a value equal to the force necessary to deliver the first material through the tube in un-occluded state, and the delta value being assigned a value selected to create a desired level of sensitivity. If a turbulence factor is less than a threshold value, the baseline value is equal to a second force, being a low-pass filtered version of the first force, the turbulence factor being a low-pass filtered version of the absolute value of the difference between the first force and the second force, measure a third force needed to deliver a second material through the tube, and determine that an occlusion exists in the tube if the third force is greater than the baseline value plus the delta value.

[007] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only, and should not be considered restrictive of the scope of the invention, as described and claimed. Further, features and/or variations may be provided in addition to those set forth herein. For example, embodiments of the invention may be directed to various combinations and sub-combinations of the features described in the detailed description.

## BRIEF DESCRIPTION OF THE DRAWINGS

[008] The accompanying drawing, which is incorporated in and constitutes a part of this disclosure, illustrates one preferred embodiment and aspect of the present invention.

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[009] FIG. 1 is a flow chart of an exemplary occlusion detection method consistent with the present invention; and

[010] FIG. 2 is a flow chart of an alternate exemplary occlusion detection method consistent with the present invention

## DETAILED DESCRIPTION

[011] The following detailed description refers to the accompanying drawing. Wherever possible, the same reference numbers are used in the drawing and the following description to refer to the same or similar parts. While a presently preferred embodiment and features of the invention are described herein, modifications, adaptations and other implementations are possible, without departing from the spirit and scope of the invention. For example, substitutions, additions or modifications may be made to the components illustrated in the drawing, and the exemplary methods described herein may be modified by substituting, reordering or adding steps to the disclosed methods. Accordingly, the following detailed description does not limit the invention. Instead, the proper scope of the invention is defined by the appended claims.

[012] Instead of having the conventional system's fixed baseline value, the baseline value of the invention may vary in embodiments consistent with the invention. How and when the baseline value varies may determine the sensitivity to small deliveries of insulin, and prevent slow changing outside force variations from causing false occlusion warnings. Several variables may be used in embodiments consistent with the invention. For example:

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i) "F" may comprise the force used to deliver the insulin, for example. This can be either pre or post delivery, but pre-delivery has some advantages;

ii) "Filtered-F" may comprise a low-pass filtered version of the force "F";

iii) "Baseline" may comprise a value at which the un-occluded Force "F" should stay near;

iv) "Delta" may comprise the amount of force above the baseline value that may trigger an occlusion warning. This is generally set to one of several fixed values which determine the level of sensitivity desired.

v) "Turbulence" may comprise a measure of how smooth "F" is relative to "Filtered-F". A larger number indicates that "F" is wandering further away from "Filtered-F".

[013] An algorithm for detecting an occlusion may include recalculating at least some of the above variables each time a delivery is made. First, "F" may be checked to make sure it does not exceed the baseline value plus the delta. If "F" does exceed the baseline value plus the delta, then an occlusion condition may exist. If no occlusion exists (for example, when "F" is less than or equal to baseline value plus delta), other variables may be recalculated and updated. This algorithm may be repeated for each delivery.

[014] Turbulence may be a function of the volatility of "F" relative to "Filtered-F". For example, one representation of turbulence may be a low-pass filtered version of the absolute value of the difference between "F" and "Filtered-F". If the turbulence is less than a predefined level, then a new baseline value may be established by setting the baseline value equal to the filtered-F.

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[015] Reading the force before the delivery may allow forces not related to the occlusion to relax, and therefore to not interfere with true occlusion detection. A large delivery of insulin could be used to desensitize the algorithm for a short period. This allows for a combination of deliveries of large "boluses" mixed with smaller "basal" deliveries. If the previous delivery was too recent, or very large, then a short term desensitizing of the algorithm may be advantageous. This may facilitate multiple deliveries back-to-back such as extended or combined deliveries that occur immediately before or after a basal delivery.

[016] The algorithm may be desensitized for a period after a new cartridge of insulin is loaded into the pump. This is advantageous because there is a period after a new cartridge is loaded in which delivery force will vary more. Furthermore, the algorithm could be dynamic depending on the size of the delivery. For example, the delta could be a function of the number of units delivered in the last n minutes.

[017] Moreover, the algorithm results could be saved to an internal memory for later analysis in order to refine the parameters. For example, the parameters could be stored in a non-volatile memory that may be read or altered by a manufacturer through an interface port. This may allow custom variations of the algorithm that may help tailor the device to the needs of a particular patient.

[018] Consistent with the invention, a system for detecting an occlusion in a tube comprises a memory storage for maintaining a plurality of data registers and a processing unit coupled to the memory storage. The processing unit is operative to receive a first force needed to deliver a first material through the tube. Furthermore, the processing unit is operative to indicate that an occlusion exists in the tube if the

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first force is greater than a baseline value plus a delta value, the baseline value being assigned a value equal to the force necessary to deliver the first material through the tube in an un-occluded state and the delta value being assigned a value selected to create a desired level of sensitivity. Moreover, the processing unit is operative to set, if the first force is less than or equal to the first baseline plus the delta value, and if a turbulence factor is less than a threshold value, the baseline value equal to a second force, this second force being a low-pass filtered version of the first force, the turbulence factor being a low-pass filtered version of the absolute value of the difference between the first force and the second force. In addition, the processing unit is operative to receive a third force needed to deliver a second material through the tube and indicate that an occlusion exists in the tube if the third force is greater than the baseline plus the delta value.

[019] FIG. 1 is a flow chart setting forth the general stages involved in an exemplary method for detecting an occlusion in a tube consistent with the invention. Exemplary ways to implement the stages of method 100 will be described in greater detail below. Exemplary method 100 begins at starting block 105 and proceeds to stage 110 where a processing unit receives a signal corresponding to a first force needed to deliver a first material through the tube. For example, in the context of a insulin infusion pump, the first force may be the force needed to deliver a first insulin dose through an infusion set into a user's body.

[020] From stage 110, where the processing unit receives a signal corresponding to the first force needed to delivery the first material through the tube, exemplary method 100 continues to decision block 120 where it is determined

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whether the first force is greater than a baseline value plus a delta value. If it is determined at decision block 120 that the first force is greater than the baseline value plus the delta value, exemplary method 100 continues to stage 130 where the processing unit indicates that an occlusion exists in the tube. If it is determined at decision block 120, however, that the first force is not greater than the baseline value plus the delta value, exemplary method 100 continues to decision block 140 where it is determined whether a turbulence factor is less than a threshold value. For example, the turbulence factor may be a low-pass filtered version of the absolute value of the difference between the first force and a second force. The second force may comprise a low-pass filtered version of the first force. If it is determined at decision block 140, that the turbulence factor is less than the threshold value, exemplary method 100 continues to decision block 150 where the processing unit sets the baseline value equal to the second force.

[021] Once the processing unit sets the baseline value equal to the second force, being a low-pass filtered version of the first force at decision block 150, or proceeds from decision block 140 if it is determined that the turbulence factor is not less than a threshold value, exemplary method 100 advances to stage 160 where the processing unit determines a third force needed to deliver a second material through the tube. For example, in the context of an insulin infusion pump, the third force may be the force needed to deliver a second insulin dose through the infusion set into the user's body.

[022] After the processing unit determines the third force needed to deliver the second material through the tube in stage 160, exemplary method 100 continues

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to stage 170 where the processing unit indicates that an occlusion exists in the tube if the third force is greater than the baseline value plus the delta value. From stage 170 where the processing unit indicates that an occlusion exists in the tube if the third force is greater than the baseline value plus the delta value, or proceeding from stage 130 where the processing unit indicates that an occlusion exists in the tube, exemplary method 100 ends at stage 180.

[023] While certain features and embodiments of the invention have been described, other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the embodiments of the invention disclosed herein. Furthermore, although embodiments of the present invention have been described as being associated with data stored in memory and other storage mediums, one skilled in the art will appreciate that these aspects can also be stored on or read from other types of computer-readable media, such as secondary storage devices, hard disks, floppy disks, a CD-ROM, a carrier wave from the Internet, or other forms of RAM or ROM. Further, the steps of the disclosed methods may be modified in any manner, including by reordering steps and/or inserting or deleting steps, without departing from the principles of the invention.

[024] It is intended, therefore, that the specification be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims and their full scope of equivalents.

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WHAT IS CLAIMED IS:

1. A method for detecting an occlusion in a tube, the method comprising:

receiving a signal corresponding to a first force needed to deliver a first material through the tube;

indicating that an occlusion exists in the tube if the first force is greater than a baseline value plus a delta value, the baseline value being assigned a value equal to the force necessary to deliver the first material through the tube in an un-occluded state and the delta value being assigned a value selected to create a desired level of sensitivity;

setting, if the first force is less than or equal to the first baseline value plus the delta value, and if a turbulence factor is less than a threshold value, the baseline value equal to a second force, in second force being a low-pass filtered version of the first force, the turbulence factor being a low-pass filtered version of the absolute value of the difference between the first force and the second force;

receiving a signal corresponding to a third force needed to deliver a second material through the tube; and

indicating that an occlusion exists in the tube if the third force is greater than the baseline value plus the delta value.

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2. A system for detecting an occlusion in a tube, the system comprising:

a memory storage for maintaining a plurality of data registers; and

a processing unit coupled to the memory storage, wherein the processing unit is operative to

receive a signal corresponding to a first force needed to deliver a first material through the tube;

indicate that an occlusion exists in the tube if the first force is greater than a baseline value plus a delta value, the baseline value being assigned a value equal to the force necessary to deliver the first material through the tube in an un-occluded state and the delta value being assigned a value selected to create a desired level of sensitivity;

set, if the first force is less than or equal to the first baseline value plus the delta value, and if a turbulence factor is less than a threshold value, the baseline value equal to a second force, the second force being a low-pass filtered version of the first force, the turbulence factor being a low-pass filtered version of the absolute value of the difference between the first force and the second force;

receive a signal corresponding to a third force needed to deliver a second material through the tube; and

indicate that an occlusion exists in the tube if the third force is greater than the baseline value plus the delta value.

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## ABSTRACT OF THE DISCLOSURE

Systems and methods for detecting an occlusion in a tube. Systems and methods may include receiving a signal corresponding to a first force needed to deliver a first material through the tube. Furthermore, the systems and methods may include indicating that an occlusion exists in the tube if the first force is greater than a baseline value plus a delta value, the baseline value being assigned a value equal to the force necessary to deliver the first material through the tube in an un-occluded state and the delta value being assigned a value configured to create a desired level of sensitivity. Moreover, the systems and methods may include setting, if the first force is less than or equal to the first baseline value plus the delta value, and if a turbulence factor is less than a threshold value, the baseline value equal to a second force, the second force being a low-pass filtered version of the first force, the turbulence factor being a low-pass filtered version of the absolute value of the difference between the first force and the second force.

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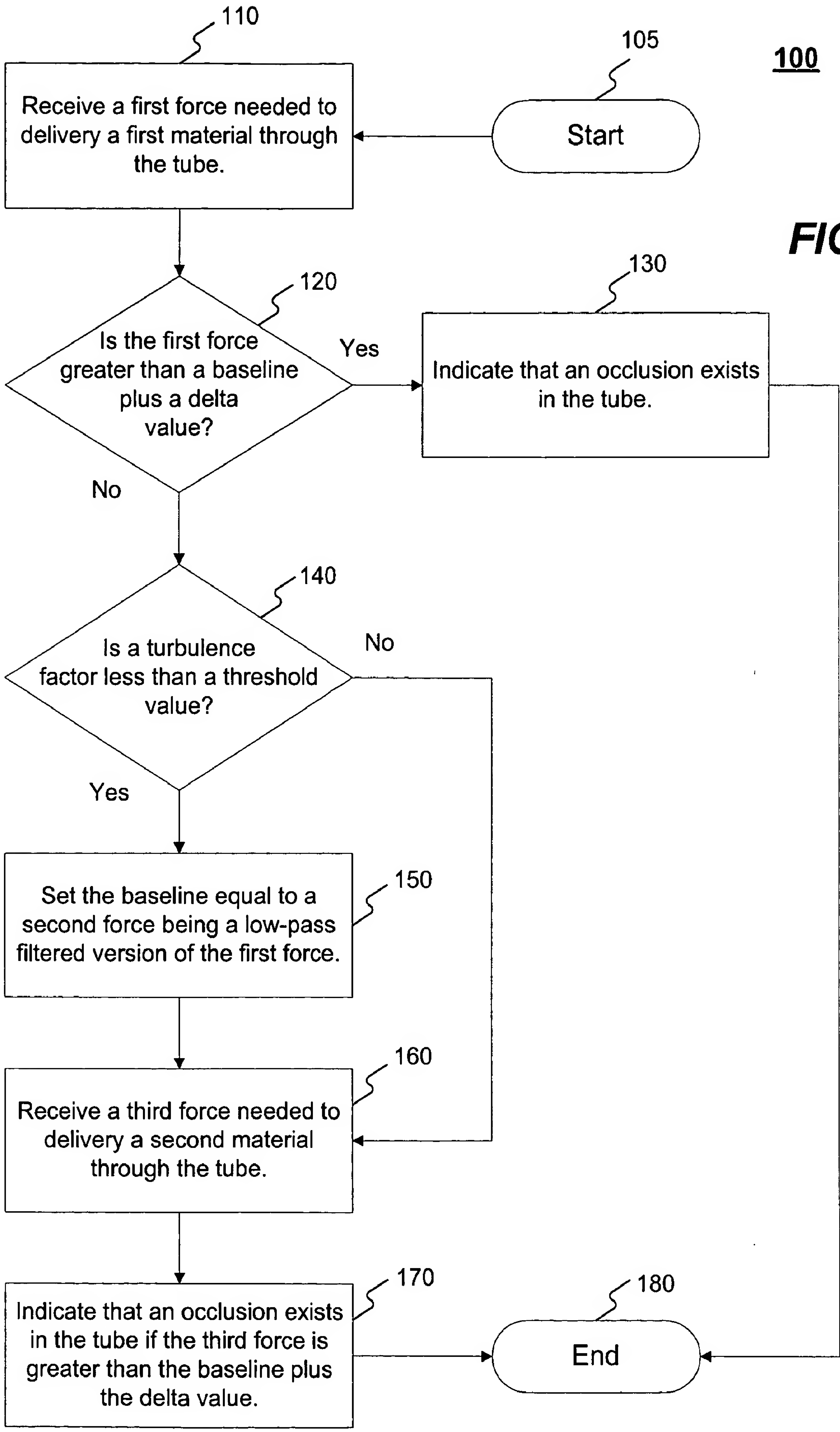
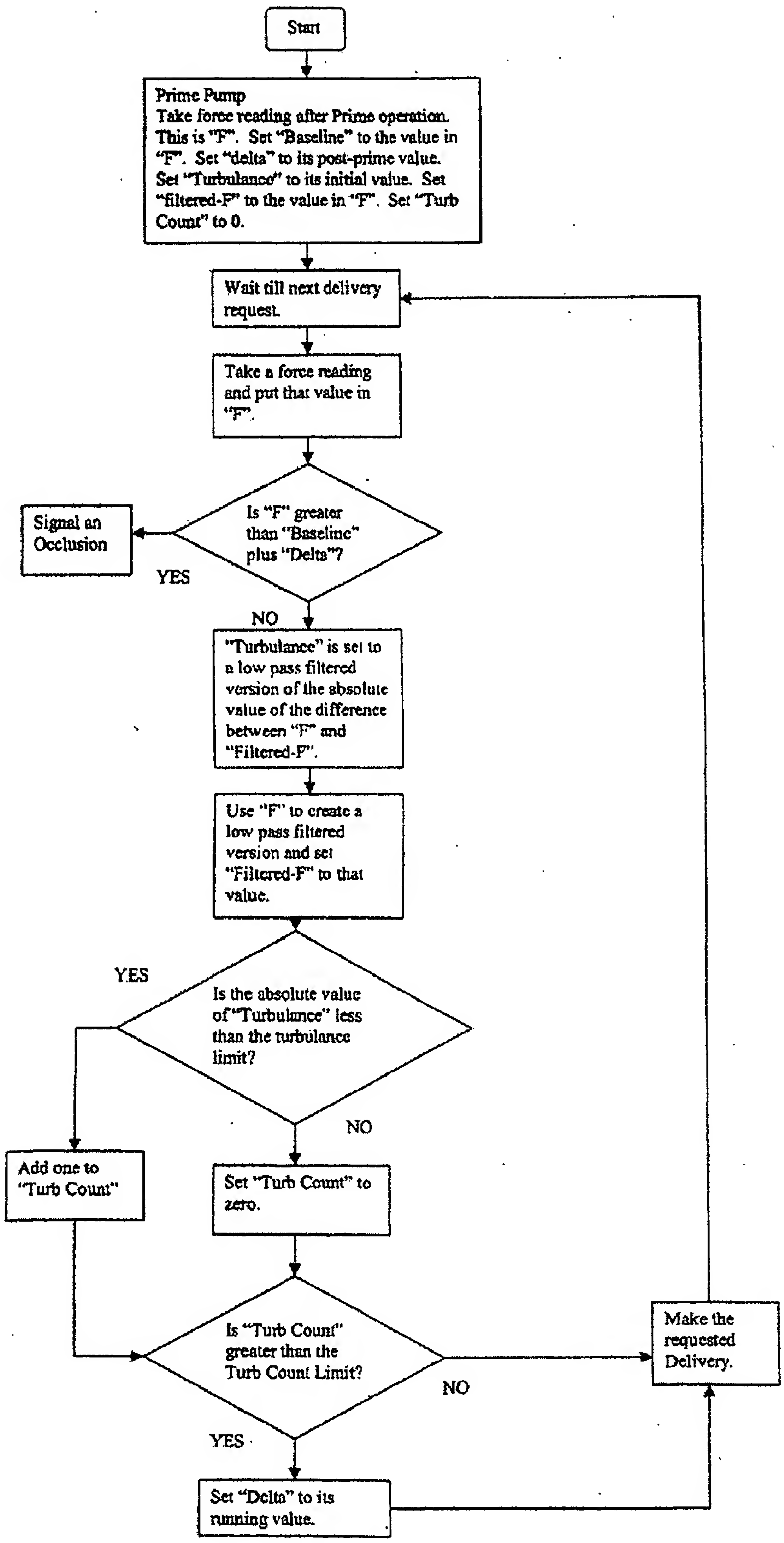

110
105
100
Start
Receive a first force needed to delivery a first material through the tube.
120
Is the first force greater than a baseline plus a delta value?
Yes
No
130
Indicate that an occlusion exists in the tube.
140
Is a turbulence factor less than a threshold value?
No
Yes
150
Set the baseline equal to a second force being a low-pass filtered version of the first force.
160
Receive a third force needed to delivery a second material through the tube.
170
Indicate that an occlusion exists in the tube if the third force is greater than the baseline plus the delta value.
180
End

FIG. 1

FIG. 2



Start
Prime Pump
Take force reading after Prime operation. This is "F". Set "Baseline" to the value in "F". Set "delta" to its post-prime value. Set "Turbulance" to its initial value. Set "filtered-F" to the value in "F". Set "Turb Count" to 0.
Wait till next delivery request.
Take a force reading and put that value in "F".
Is "F" greater than "Baseline" plus "Delta"?
YES
Signal an Occlusion
NO
"Turbulance" is set to a low pass filtered version of the absolute value of the difference between "F" and "Filtered-F".
Use "F" to create a low pass filtered version and set "Filtered-F" to that value.
Is the absolute value of "Turbulance" less than the turbulance limit?
YES
Add one to "Turb Count"
NO
Set "Turb Count" to zero.
Is "Turb Count" greater than the Turb Count Limit?
NO
Make the requested Delivery.
YES
Set "Delta" to its running value.